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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,640	01/18/2001	Ming-Hui Wei	CL000964-CIP	6098

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CELERA GENOMICS CORP.

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1636

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6

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/761,640

Applicant(s)

WEI ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claims 1-23 are pending in the present application, and they are subjected to the following restriction.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2 and 20-21, drawn to an isolated peptide consisting of or comprising an amino acid sequence selected from the recited group, classified in class 530, subclasses 300 and 350.
- II. Claim 3, drawn to an isolated antibody that selectively binds to a peptide of the present invention, classified in class 424, subclass 130.1.
- III. Claims 4-5, 8-11 and 22-23, drawn to an isolated nucleic acid molecule consisting of or comprising a nucleotide sequence selected from the recited group; a nucleic acid vector and a host cell comprising the same; and a method for producing one of the peptides of the present invention using the same, classified in class 536, subclass 23.2; class 435, subclasses 320.1, 69.1, 455, for examples.
- IV. Claim 6, drawn to a gene chip comprising a nucleic acid molecule of the present invention, classified in class 435, subclass 174.
- V. Claim 7, drawn to a transgenic non-human animal comprising a nucleic acid molecule of the present invention, classified in class 800, subclass 8.

- VI. Claim 12, drawn to a method for detecting the presence of any of the peptides of the present invention in a sample, comprising contacting said sample with a detection agent that specifically allows detection of the presence of the peptide in the sample, classified in class 435, subclass 7.1.
- VII. Claim 13, drawn to a method for detecting the presence of a nucleic acid molecule of the present invention in a sample, comprising contacting the sample with an oligonucleotide that hybridizes to said nucleic acid molecule under stringent conditions and determining whether the oligonucleotide binds to said nucleic acid molecule in the sample, classified in class 435, subclass 6.
- VIII. Claims 14-15, drawn to a method for identifying a modulator of a peptide of the present invention, comprising contacting the peptide with an agent and determining if said agent has modulated the function or activity of said peptide, classified in class 435, subclass 4.
- IX. Claim 16, drawn to a method for identifying an agent that binds to any of the peptides of the present invention, comprising contacting the peptide with an agent and assaying the contacted mixture to determine whether a complex is formed with an agent bound to the peptide, classified in class 435, subclass 4.
- X. Claims 17-18, drawn to a pharmaceutical composition comprising an agent identified by the method of claim 16, and a method for treating a

disease or condition mediated by a human phosphatase protein using the same identified agent, can not be classified because the nature of the agent is not identified.

- XI. Claim 19, drawn to a method for identifying a modulator of the expression of a peptide of the present invention, comprising contacting a cell expressing said peptide with an agent and determining if said agent has modulated the expression of said peptide, classified in class 435, subclass 4.

Should Applicants elect one of the inventions of Groups I to IX and XI, **further group restrictions are required**. Claims 1-23 link a plurality of patentably distinct amino acid sequences of SEQ ID NOs: 2, 5 and 7 that are encoded by patentably distinct cDNA sequences of SEQ ID NOs: 1, 4 and 6, respectively, and by the genomic nucleic acid sequence of SEQ ID NO:3 that lack the unity of invention. As set forth in MPEP 803.02, unity of invention exists if all species recited in a claim (1) shows a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility. There is no substantial obvious common core structures shared among the various spliced forms of a human phosphatase having SEQ ID NOs: 2, 5 and 7, nor is there any evidence indicating that these spliced forms possess the same or similar phosphatase activity. Additionally, there is also no substantial obvious common core structure among the cDNA sequences of SEQ ID NOs: 1, 4, 6 and the genomic sequence of SEQ ID NO:3. Thus, claims 1-23 improperly link multiple distinct inventions. Applicants are required under 35 U.S.C. 121 to elect a specific amino acid

SEQ ID NO or its corresponding cDNA sequence or the genomic SEQ ID NO: 3. This is not a species restriction.

The inventions are distinct, each from the other because of the following reasons:

The isolated peptide of Group I, the isolated antibody of Group II, the isolated nucleic acid molecule of Group III, the gene chip of Group IV, the transgenic non-human animal of Group V and the pharmaceutical composition of Group X are chemically and structurally distinct one from the others. For examples, the isolated peptide of Group I is composed of amino acid residues, the isolated antibody of Group II is made of a distinct amino acid sequence that has the ability to bind specifically to the isolated peptide of Group II, the isolated nucleic acid molecule of Group III is composed of nucleotide residues, the gene chip of Group IV is physically and materially distinct from the compositions of Groups I-IV, the transgenic non-human animal of Group V is a living entity whereas the pharmaceutical composition of Group X comprises an unidentified agent obtained from the screening method of the present invention.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because the methods in Groups III, VI to XI constitute patentably distinct inventions. The methods of Groups III, VI to XI involve different starting materials, different method steps and different technical considerations for attaining different desired end-results. For examples, the invention of Group III is drawn to a method for producing any of the peptides of the present invention by culturing a recombinant host cell; the invention of Group VI is directed to a method for

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detecting the presence of any of the peptides of the present invention in a sample using a detection agent; the invention of Group VII is drawn to a method for detecting the presence of a nucleic acid molecule of the present invention in a sample using an oligonucleotide under a stringent hybridizing conditions; the invention of Group VIII is directed to a method for identifying a modulator of a peptide of the present invention by screening for an agent that has modulated the function or activity of the peptide; the invention of Group IX is simply drawn to a method for identifying an agent that binds to any of the peptides of the present invention; the invention of Group X is directed to a method of treating a disease or condition mediated by a human phosphatase protein using an agent whose nature is not disclosed; and the invention of Group XI is drawn to a method for identifying a modulator of the expression of a peptide of the present invention using a cell expressing said peptide. Additionally, the methods of Groups III, VI to XI can be carried out independently one from the other.

Inventions of Group I and Groups VIII, IX are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated peptide of Group I can be used to prepare the isolated antibody of Group II.

Inventions I and VI-VII, XI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

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808.01). In the instant case the isolated peptide of Group I is not required for the practice of any of the methods of Groups VI-VII, X and XI. For example, how can the isolated peptide of Group I be used in a hybridization assay under stringent conditions for detecting the presence of a nucleic acid molecule in the method of Group VII? Or the isolated peptide of Group I can modulate its own expression in a cell in a method of Group XI.

Inventions of Group II and Groups VI, VIII, IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated antibody of Group II can be utilized for the purification of any of the peptides of claim 2, and that the methods of Groups VI, VIII, IX do not require specifically the use of an antibody for detecting the presence of one of the peptides of claim 2 or for identifying a modulator of the peptide or an agent that binds to the peptide (e.g., a labeled binding agent that specifically binds to any of the peptides of claim 2).

Inventions II and VII, X-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the isolated antibody of Group II is not required for the practice of the methods of Groups VII and X-XI. For example, how can the isolated antibody of Group II be used in a hybridization assay under stringent conditions for

detecting the presence of a nucleic acid molecule in the method of Group VII? Or the isolated antibody of Group II can modulate the expression of a peptide in claim 2 in a cell in a method of Group XI.

Inventions of Group III and Groups VII, XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated nucleic acid molecule of Group III can be utilized in a method for producing recombinant peptides of the present invention in an isolated host cell in cultures as evidenced by claims 10-11.

Inventions III and VI, VIII-X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the isolated nucleic acid molecule of Group III is not required for the practice of the methods of Groups VI, VIII-X. For example, how can the isolated nucleic acid molecule of Group III be used in a method for detecting the presence of any of the peptides of the present invention in the method of Group VI? Or the isolated nucleic acid molecule of Group III be used to identify a modulator of a peptide of the present invention in the method of Group VIII.

Inventions IV and VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the gene chip of Group IV is not required for the practice of any of the methods of Groups VI-XI. For example, how can the gene chip of Group IV be used in a method for detecting the presence of any of the peptides of the present invention in the method of Group VI? Or the gene chip of Group IV be used to identify a modulator of a peptide of the present invention in the method of Group VIII.

Inventions V and VI-XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the transgenic non-human animal of Group V is not required for the practice of any of the methods of Groups VI-XI. For example, how can the transgenic non-human animal of Group V be used in a method for detecting the presence of any of the peptides of the present invention in a sample in the method of Group VI? Or the transgenic non-human animal of Group V be used to identify a modulator of a peptide of the present invention in a host cell in the method of Group VIII.

Inventions X and VI-IX and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the pharmaceutical composition of Group X is not required for the practice of any of the methods of Groups VI-IX and XI. For example, how can the pharmaceutical composition of Group X be used in a method for detecting the presence of a nucleic acid molecule of the present invention in a sample in the method

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of Group VII? Or the pharmaceutical composition of Group X be used in an assay method for identifying a modulator of the expression of a peptide of the present invention in a cell in the method of Group XI.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and separate search requirements, it would be unduly burdensome for the examiner to search and/or consider the patentability of all the inventions in a single application. Particularly, the teachings of an art for the amino acid sequence of SEQ ID NO:2 would not have been obvious for the amino acid sequence of SEQ ID NO:5 or SEQ ID NO:7. Similarly, the teachings of an art for the nucleic acid sequence of SEQ ID NO:1 would not have been obvious for the nucleic acid sequence of SEQ ID NO:3 or SEQ ID NO:4 or SEQ ID NO:6. Therefore, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, Gerald Leffers, Jr., Ph.D., may be reached at (703) 305-6232, or SPE, Remy Yucel, Ph.D., at (703) 305-1998.

Gerald G. Leffers Jr.
PATENT EXAMINER
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A. 4. 1636